23rd Pharmacovigilance 2020

#VIphv

"Ensuring safer drugs to market by analyzing latest developments in pharmacovigilance, drug safety and risk management"

16th December 2020, Virtual Conference (Time Zone - IST)

AGENDA AT A GLANCE

Key Speakers Include

BABITA KIRODIAN
Country Pharmacovigilance Lead
Amgen

S.SALAVADI EASWARAN
Academic Dean
Biocon Academy

ARUN BHATT
Consultant – Clinical Research & Development

OMPRAKASH S. SADHWANI
Former Joint Commissioner and controlling Authority, FDA (Maharashtra state)

INDU NAMBIAR
Head Pharmacovigilance
Boehringer Ingelheim

S.R.SALUNKHE
Former Assistant commissioner
FDA Maharashtra

MANOJ SWAMINATHAN
Chief Manager / Head - Global Pharmacovigilance Center, Piramal

JAMAL BAIG
Country Head- Pharmacovigilance
Merck Sharp & Dohme

RANJIT BARSHIKAR
QbD / CGMP Consulting, Member Editorial Board Journal of Generic Medicines, England

PAVAN BADALE
Head- PV Process Excellence, Safety case Management, Novartis

DHANARAJ E
Pharmacovigilance Lead
Biocon

JYOTSNA PATWARDHAN
Head Development QA
Novartis

SAKHARAM GARALE
Head South-East Asia Operations ACMA & Managing Partner, RENOVARE Healthcare Solutions

KAVYA KADAM
Consultant Global Clinical Trials

Plus more COMING SOON.....

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CONFERENCE INTRODUCTION

Virtue insight's 23rd Pharmacovigilance Conference is more than a traditional conference. It is a unique opportunity to learn about the latest trends, to engage with renowned experts, and to personally develop as a healthcare professional. The **23rd Pharmacovigilance Conference** will take place virtually for the very first time on **16th December 2020.**

This conference provides the foundation for strong strategic planning and practical decision-making in your pharmacovigilance programs. This year's conference will address the current thinking on predicting and assessing risks such as drug-induced liver injury, and the assessment of expectedness of serious adverse reactions during clinical development. The complexities of assessing benefit-risk balance of today's therapies, including immunotherapy and other advanced therapies, will be examined. Experts will present approaches and engage in dialogs around more extensive and impactful uses of real world data and generation of RWE for safety assessments. A full-day will be devoted to the development, implementation, and assessment of risk management strategies for drugs approved in multiple regions.

Take the opportunity to learn from regulators and leading experts and discover what the challenges and opportunities will be in the field of Pharmacovigilance in 2020.

Do not miss out on these exciting discussions. Join us virtually to discover and learn from the experts who will be joining us on 16th December 2020.

We look forward to seeing you there!

KEY THEMES DISCUSSED

- Review, predictions & updates on the global pharmacovigilance market
- Key regulations and pharmacovigilance system
- Pharmacovigilance and its importance in the pharmaceutical industry expands
- Discussion of pharmacovigilance and its effect in healthcare and patient care
- Demand for pharmacovigilance and consumer research
- Addressing concerns with drug safety by recognizing the risks associated with pharmaceutical products and reducing the possibility of any potential harm to patients
- Present legislation and proposals for pharmaceutical drugs endorse and carry out post marketing drug tests
- Planning pharmacovigilance and risk management
- Concentrating on the pharmacovigilance regulatory system in the form of risk management planning
- A performance risk management strategy across the drug development lifecycle
- The complexities of communicating and controlling the established quality risks
- Addressing global perspective of pharmacovigilance and risk management strategies
- Discussing about improving health outcomes and patient safety
- Real world evidence: The evolving regulatory landscape, information and integrated usage
- How real-world data is used today to produce evidence in major markets
- A new approach and support towards pharmacovigilance regulations
- New regulatory guidelines and laws governing pharmacovigilance
- Be part of a major networking opportunity

WHO SHOULD ATTEND AND WHO YOU'LL MEET

Vice Presidents, Directors, CRO's, Heads and Managers of:

Pharmacovigilance Strategy, Drug Safety/Risk Management, Information and Clinical Data Management, Clinical Research, Research & Development, Product Safety/Assurance Assessment, Patient Safety & Outcomes Research & Data Analysis, Epidemiology project management, Regulatory Affairs and Compliance, Sales & Marketing, Biotech manufacturers

From the following :

Pharmaceutical organizations, Generic pharmaceutical companies, Contract research organizations, Patient recruitment companies, Government- Department of health, Non-profit organizations/ Association, Consultants

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DAY ONE - 16th December 2020

09:20 - Chairperson opening remarks

RANJIT BARSHIKAR
QbD / CGMP Consulting, Member Editorial Board Journal of Generic Medicines, England

MARKET OVERVIEW & ANALYSIS

09:30 – Discussion of the demand for pharmacovigilance and consumer research

- Review and predictions on the global pharmacovigilance market
- Global pharmacovigilance, drug safety, market size growth, and revenue analysis
- Addressing the recent financial developments while analysing the growth of the key market players
- Total review of current and emerging trends and opportunities

10:00 – Discussing updates on pharmacovigilance in India

- Key regulations and pharmacovigilance system
- Current Pharmacovigilance conditions and requirements in India
- Understanding the important issues that need to be ad dressed
- Main problems to tackle when implementing systems and choosing vendors

10:30 – Morning Coffee/Tea & Discussion

CHALLENGES & OPPORTUNITIES

10:50 – DISCUSSION WITH EXPERTS: Pharmacovigilance and its importance in the pharmaceutical industry expands

- Discussion of pharmacovigilance and its effect in healthcare and patient care
- Pharmacovigilance laws and a view on the laws and restrictions to be observed in pharmacovigilance
- Discussing on pharmaceutical industry problems in developing pharmacovigilance networks
- Scientific discussion in the field of pharmacovigilance in herbal medicines
- Detection and assessment of drug safety signals via reporting by manual and medical devices
- Challenges of improving drug protection and maintaining public trust

Moderator:

DHANARAJ E
Pharmacovigilance Lead
Biocon

Panellists:

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Country Pharmacovigilance Lead
Amgen

JAMAL BAIG
Country Head- Pharmacovigilance
Merck Sharp & Dohme

MANOJ SWAMINATHAN
Chief Manager / Head - Global Pharmacovigilance Center, Piramal

INDU NAMBIAR
Head Pharmacovigilance
Boehringer Ingelheim

11:30 – DISCUSSION WITH EXPERTS: Addressing concerns with drug safety by recognizing the risks associated with pharmaceutical products and reducing the possibility of any potential harm to patients

- Present legislation and proposals for pharmaceutical drugs endorse and carry out post-marketing drug tests
- Addressing the safety issues contained in the risk man agement program and regular steps to reduce potential risks.
- Address safety issues regarding drug errors and risk minimization measures in India for centrally approved products
- Addressing drug safety issues which includes the development of tools, techniques, and data sources that helps to better identifying and managing safety issues related to drug effects and product quality
- Develop new and creative methods to enhance the capabilities of testing drug products.
- Discussing and applying complex data to identify safety and effectiveness concerns and support informed decision-making

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Head- PV Process Excellence, Safety case Management
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SAKHARAM GARALE
Head South-East Asia Operations ACMA & Managing Partner, RENOVARE Healthcare Solutions

12:10 – Challenges of Clinical Trial Safety Management during a Pandemic

ARUN BHATT
Consultant – Clinical Research & Development

12:40 - Networking luncheon

Afternoon Chair Person

13:50 – Applications of Artificial Intelligence Tools in Enhancing Decision Making in Pharmacovigilance Program

S.SALAVADI EASWARAN
Academic Dean
Biocon Academy

14:20 – DISCUSSION WITH EXPERTS: Addressing global perspective of pharmacovigilance and risk management strategies

- Discussing about improving health outcomes and patient safety
- Approaches when managing drug benefits and risks
- Additional measures other than product labeling while communicating a risk or influencing a health care provider and patient behavior
- Addressing the risk reduction approaches that various regulatory agencies accept
- Identify situations where the REMS and the risk management programs vary in compliance
- Discuss approaches for risk management which have been effectively applied in a dynamic global context

Moderator:

Panellists:

JYOTSNA PATWARDHAN
Head Development QA
Novartis

KAVYA KADAM
Consultant Global Clinical Trials

15:10 – Afternoon Tea/Coffee

15:30 – Real world evidence: The evolving regulatory landscape, information and integrated usage

- How real-world data is used today to produce evidence in major markets
- Concentrating on generating facts for regulatory use
- Whether the reliability of proof from real-world data for every use case is evaluated
- Current status of FDA guidance

16:00 – DISCUSSION WITH EXPERTS: A new approach and support towards pharmacovigilance regulations

- New regulatory guidelines and laws governing pharmacovigilance

DAY ONE - 16th December 2020

- Discussion of the directives and regulations which constitute the greatest shift in the regulation of human medicine
- Post-authorisation regulatory standards that must be adhered by the applicant to ensure compliance with the FDA
- Focusing on the need to refine Pharmacovigilance regulatory standards in India
- Maintain close relations with drug regulatory authority to ensure that the latter are well educated in regular clinical practice about safety issues

Moderator:

Panellists:

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17:40 - Chairperson's closing remarks and end of conference

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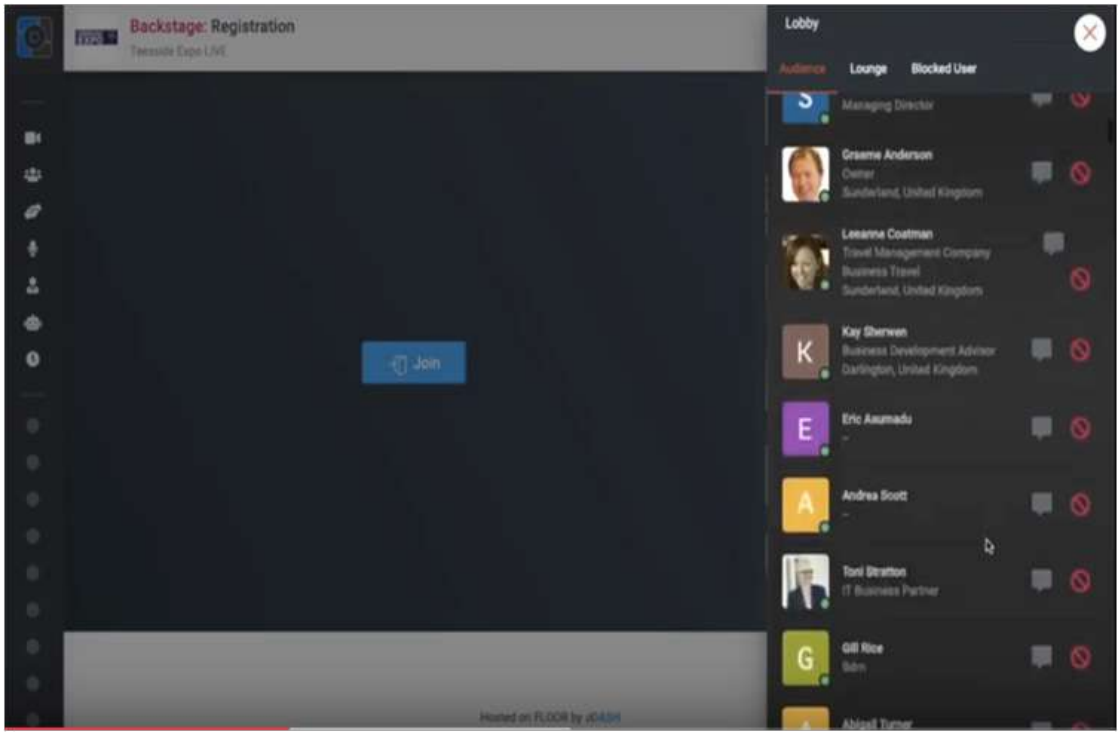
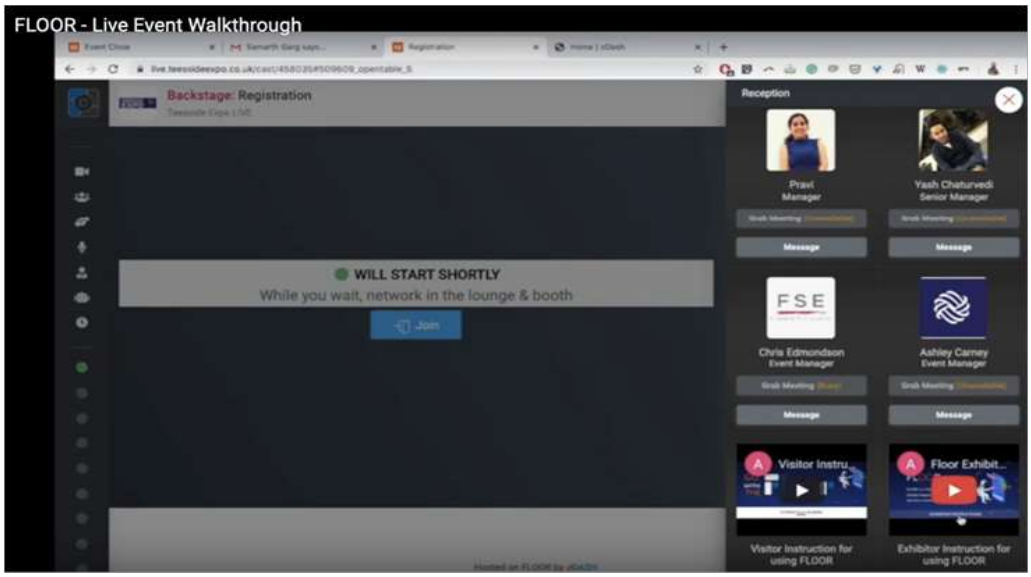
Features of our Virtual Conference

NETWORKING

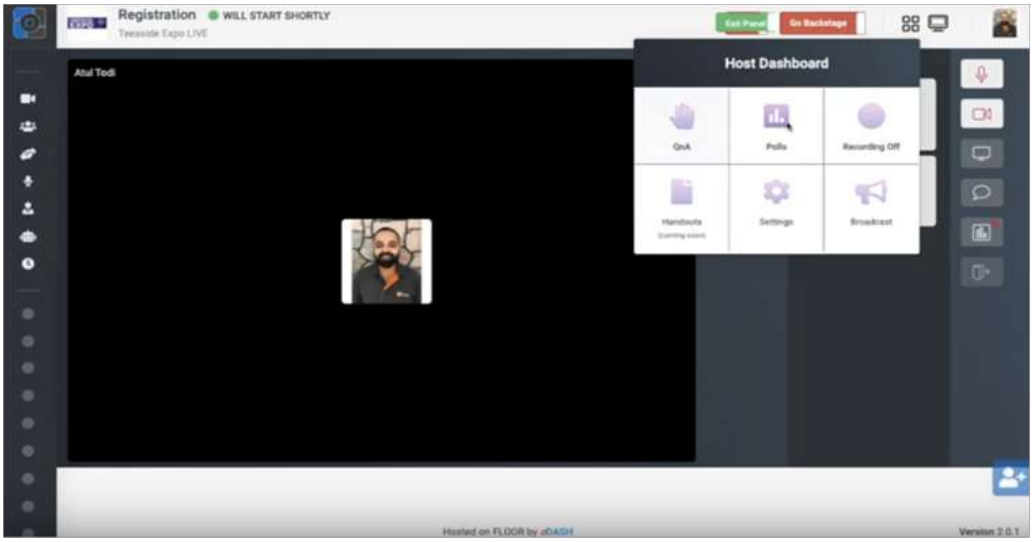
Lobby – Here at the lobby, all attendees can see the other participants. You can choose to start a conversation privately at any time with any of the other co-participants– For more details – check out the links (YouTube videos in the last page)



Reception – Should you have any questions to the organisers, you can find them at the reception - For more details – check out the links (YouTube videos in the last page)



Q&A, Polls & Handouts– We can have Q&A from the audience at the end of every session as usual and also have polls and handouts done - For more details – check out the links (YouTube videos in the last page)



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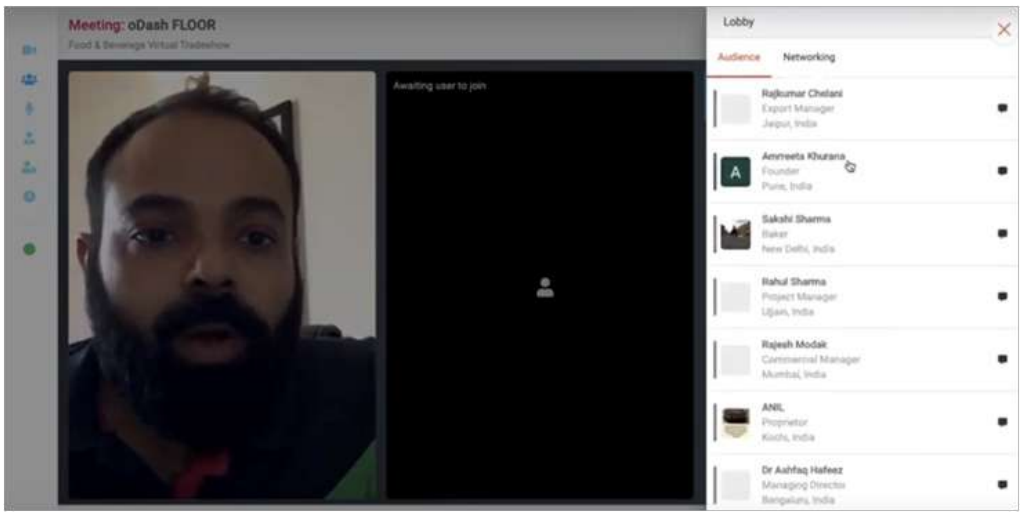
LIVE STREAMING

Solo Presentations & Panel Sessions– Interactive panel sessions and solo presentations sessions - For more details – check out the links (YouTube videos in the last page)

SPONSORS & EXHIBTORS

Exhibitors– Exhibitors have booths where they can start a conversation with any of the attendees and also attend to the attendees who visit their stall - For more details – check out the links (YouTube videos in the last page)



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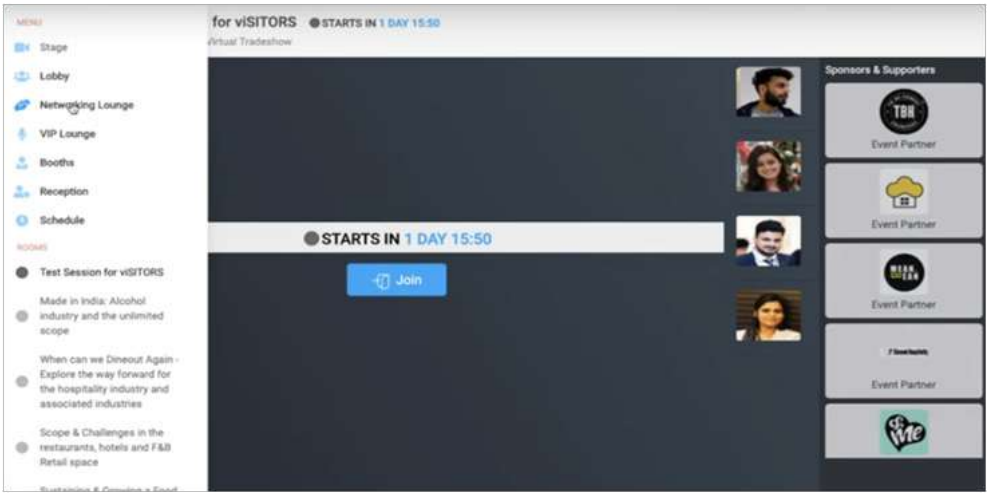
Sponsors– Sponsors can have speaking slot sessions and their logos would be visible in all sessions for their branding purposes - For more details – check out the links (YouTube videos in the last page)



Links to YouTube videos of the conference webinar platform

Live Event Walkthrough - https://www.youtube.com/watch?v=KRX5j3gQeF0

Exhibitor Instructions - https://www.youtube.com/watch?v=uOvH46TeYrw

Visitor Instructions - https://www.youtube.com/watch?v=c4WSfp9RFP0

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REGISTER ONLINE :

Link : https://www.bookmytrainings.com/catalogue/event/78986-23rd-pharmacovigilance-2020

For Multiple Bookings - Photocopy this form and send it to **bookings@virtueinsight.com**

REGISTRATION FORM

RESERVATION PRICING:

Early Bird Discount Price

Cost per delegate (Valid till 15th November 2020) -

Fee: INR 07,000 + GST(18%)

Standard Rate

Cost per delegate (Valid From 16th November 2020)-

Fee: INR 10,000 + GST(18%)

Discounted Rate for Bulk Booking of More Than 5 Delegates

Please email us at **bookings@virtueinsight.com**

Registration Form Details:

Forename .....Surname .....

Job Title .....

Company .....

GST No (If Applicable) .....

Official Contact Number .....

Address .....

.....

Country .....Postcode.....

Phone .....Fax .....

Email .....

I confirm that I have read & agree to the terms and conditions of booking..... (Please Tick) ☐

Signature .....

Methods of Payments:

By Cheque - Complete and return the above registration form via post or email, together with your cheque payable to Virtue Insight.

By Bank Transfer:

Account Name	- Virtue Insight
Account Type	- Current
Account Number	- 915020031763553
Bank Name	- Axis Bank
Bank Address	- 2/8 LAMBERT NAGAR, 1st cross street, Virugambakkam, Chennai - 600 092
Branch Name	- Virugambakkam, Chennai
Swift Code	- AXISINBB211
NEFT / IFSC Code	- UTIB0000211
Micro Code	- 600211010

CERTIFICATION

E-Certificate of attendance would be provided to attendees on request, upon completion of conference

Queries:

Should you have any questions on bookings,
Please feel free to contact us.

Email: info@virtueinsight.com
Web: http://www.virtueinsight.com
India Office: Tel: +91 44 42108101
UK Office: Tel: +44-20 3509 3779

TERMS AND CONDITIONS:

Payment terms: Virtue Insight requires the full amount to be paid before the conference. We may refuse entry to delegates who have not paid their invoice in full.

Cancellations: Delegates and vendors are subject to the following charges and refunds upon withdrawal or cancellation between 2-3 month's prior 75% cancellation fee/ 25% refund. Less than 2 months prior to the event Full cancellation fee / No refund.

Administration Fee: If you cancel your participation (once confirmed) and haven't paid the attendance fee you will be liable to pay an administration fee of INR 5,000

Substitutions/Name Change: If you are unable to attend you may nominate, in writing, another delegate to take your place at any time prior to the start of the event. This can be done at no extra cost.

Indemnity: Virtue Insight reserves the right to make alterations to the conference/executive briefing content, timing, speakers or venue without notice. The event may be postponed or cancelled due to unforeseen events beyond the control of Virtue Insight. If such a situation arises, we will reschedule the event.

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